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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/956,980	09/21/2001	Ashley I. Bush	0609.4550001/JAG/FRC	6687
26111	7590	05/10/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			WEDDINGTON, KEVIN E	
		ART UNIT	PAPER NUMBER	
		1614		

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/956,980	BUSH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 11 January 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 10,11,25,26,40,41 and 58-63 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 10, 11, 25, 26, 40, 41 and 58-63 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_ .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_ .

**Claims 10, 11, 25, 26, 40, 41 and 58-63 are presented for examination.**

**Applicants' response filed January 11, 2005 has been received and entered.**

**Accordingly, the rejection made under 35 USC 112, first paragraph as set forth in the previous Office action dated October 26, 2004 at pages 2-4 is hereby withdrawn.**

***Claim Rejections - 35 USC § 112***

**The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 10, 11, 25, 26, 40, 41 and 58-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating amyloidosis in a subject with the combination of bathocuproine and clioquinol, does not reasonably provide enablement for other chelators specific for copper combined with clioquinol. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.**

**In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.**

**The factors include:**

- 1) the quantity of experimentation necessary**
- 2) the amount of direction or guidance provided**
- 3) the presence or absence of working examples**

- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

**The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.**

**The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art**

The claimed invention relates to methods of treating amyloidosis in a subject, said method comprising administering to said subject an effective amount of a combination of (a) a chelator specific for copper, and (b) clioquinol; wherein said combination reduces, inhibits or otherwise interferes with alpha beta-mediated production of radical oxygen species and prevents formation of alpha beta amyloid, promotes, induces or otherwise facilitates resolubilization of alpha beta deposits, or both.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the other chelators specific for copper combined with clioquinol will treat amyloidosis.

**The breadth of the claims**

The claims are very broad and inclusive to all chelators specific for copper can be combined with clioquinol.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the combination of bathocuproine and clioquinol as stated in the applicants' response dated January 11, 2005 at page 6, under **Existence of Working Examples**, to page 7, lines 1-7.

No examples showing the combination of other chelators specific for copper combined with clioquinol.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the other chelators specific for copper combined with clioquinol is effective in treating amyloidosis. The level of experimentation needed to determine the other chelators specific for copper when combined with clioquinol would be able to treat amyloidosis is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 10, 11, 25, 26, 40, 41 and 58-63 are not allowed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 11, 25, 26, 40, 41 and 58-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crow et al. (6,022,879) in view of Gerolymatos (5,980,914), all of

record, for reasons of record as set forth in the previous Office action dated October 26, 2004 as applied to claims 40, 41, 62 and 63.

Applicants' remarks regarding the prior art, the combination of Crow et al. in view of Gerolymatos, does not establish a *prima facie* case of obviousness are not persuasive since the two cited references or prior art, individually, teaches a chelator specific for copper (bathocuproine) to treat disorders caused by amyloidosis and clioquinol to treat disorders caused amyloidosis such as Parkinson's disease. The instant rejection is based upon the well-established principle of patent law that no invention resides in combining 2 or more ingredients of known character, where the results obtained are no more than the additive effects of the individual ingredients. It has not been demonstrated on the record, by means of experimental data commensurate in scope with the claimed subject matter, that applicants' combination produces any unobviousness or unexpected results. The mere arguments of applicants are insufficient to overcome the strong *prima facie* case of obviousness without the experimental data.

Claims 10, 11, 25, 26, 40, 41 and 58-63 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

**Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).**

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
May 6, 2005